K020267

MAR 2 9 2002

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 West Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
(714) 516-7488 – Facsimile
Colleen Boswell – Contact Person

Date Summary Prepared: January 2002

Device Name:

- Trade Name – *Optilux Curing Lights*
- Common Name – Curing Light
- Classification Name – Ultraviolet activator for polymerization, per 21 CFR § 872.6070

Devices for Which Substantial Equivalence is Claimed:

- Kerr Corporation, *Optilux 400*

Device Description:

The *Optilux Curing Lights, Models 380, 401 and 405*, are devices used for the polymerization of dental materials using visible light. They consist of a control unit and cord connected handpiece. The molded plastic control units house the printed circuit board with control circuitry for the lamp and cooling fan. Additionally, the printed circuit board for the *Model 380* contains control circuitry for radiometer functions. *Model 380* also has a permanently attached power cord, however the power cords on *Models 401 and 405* are detachable. The handpiece cord attached to the *Model 405* is separable by a panel mount connector, which allows the control unit to be installed inside a cabinet or dental chair.

The molded plastic handpieces contain a low voltage halogen lamp, optical filter assembly and a fiber optic light guide that generates visible (blue-white) light energy having a bandwidth of approximately 400 – 515 nm. The handpieces also contain a small printed circuit board with a micro-switch for activation of the curing lamp.

Intended Use of the Device:

The intended use of the *Optilux Curing Lights* are for the polymerization of light cure materials.

Substantial Equivalence:
The *Optilux Curing Lights* are substantially equivalent to other legally marketed devices in the United States. The *Optilux Curing Lights* function in a manner similar to and are intended for the same use as the *Optilux 400* designed by Kerr Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2002

Ms. Colleen Boswell
Director, Corporate Compliance
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92667

Re: K020267
Trade/Device Name: Optilux Curing Lights
Regulation Number: 872.6070
Regulation Name: Ultaviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: January 22, 2002
Received: January 25, 2002

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020267

Section I

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Kerr Corporation

510(k) Number (if known): _____

Device Name: Optilux Curing Lights

Indications For Use:

The *Optilux Curing Lights* are visible light curing units intended for polymerization of light cure materials.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020267

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)